IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Inventor(s): Jack T. JOHANSEN) Confirmation No. 3924
Appln. No. 10/508,799	Group Art Unit: 1637
Filed: September 21, 2004) Examiner: Staples, M.
Title: PURIFICATION METHODS FOR OLIGONUCLEOTIDES AND THEIR ANALOGS)))

STATEMENT OF THE SUBSTANCE OF INTERVIEW

Commissioner of Patents and Trademarks U.S. Patent and Trademark Office Customer Window Randolph Building 401 Dulany Street Alexandria, VA 22314

Sir

This statement is being filed as a follow-up to interview with Supervisory Examiner Benzion, Primary Examiner Horlick and Examiner Staples (the latter by telephone) on June 9, 2008. The applicants were represented by Chris Revell, the applicants' European patent attorney, Mark Sullivan and the undersigned. The courtesy and helpfulness of the Examiners in arranging the interview to accommodate Mr. Revell's travel schedule and in discussing the patentability issue of record are much appreciated.

The discussion at the interview centered on the differences between the applicants' invention as defined by the claims, primarily claim 1, and the Bambara disclosure. The differences discussed are brought out in the applicants' response filed on April 28, 2008. Thus, as noted at the interview and in the April 28th response, the applicants' method for separating the target oligonucleotide from an impurity involves binding the mixture of target oligonucleotide and impurity to a titratable anion exchange

composition at a first pH and passing a solution through the titratable anion exchange composition with the <u>mixture of oligonucleotide and impurity thereon</u>, the <u>pH of the solution being increased</u> over time to a <u>pH higher than the first pH</u>, the impurity being eluted at a different pH from the target oligonucleotide. According to Bambara (see page 46008, right-hand Column, first full ¶), the sample to be processed is loaded onto the support at a pH of 8.5. Bambara then passes a second solution at pH 7.5 which causes the urea impurity to elute. Thereafter, Bambara elutes the oligonucleotide using a solution of pH 8.5, i.e. the same pH as that of the solution Bambara uses for loading. This is contrary to the applicants' case where the pH of the eluting solution is <u>increased</u> over time to a pH <u>higher</u> than the first pH to elute the target oligonucleotide.

It was agreed that the Examiner would consider the matter with the Primary Examiner and advise the undersigned. Since then, on June 10th, the Examiner has telephoned to inform applicants' counsel that an Advisory Action was being issued.

Respectfully submitted,

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